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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/844,061 | 04/26/2001 | Nancy Elisabeth Krauss | R0070B-REG | 9572 |

24372 7590 05/06/2002

ROCHE BIOSCIENCE
3401 HILLVIEW AVENUE
INTELLECTUAL PROPERTY LAW DEPT., MS A2-250
PALO ALTO, CA 94304-9819

EXAMINER

LIU, HONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 05/06/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/844,061

Applicant(s)
Krauss et al.

Examiner
Hong Liu

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1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 38-43 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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DETAILED ACTION

Claims 1-19 and 38-43 are pending in this application.

This action is in response to the applicants' amendment and reply filed on March 8, 2002.

Response to Arguments

Applicants' arguments filed on March 8, 2002 have been fully considered but they are not persuasive. Rejections to Claims under 35 U.S.C. 112, first paragraph, second paragraph, 102, and 103? are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-19 and 38-43 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. applicants argue that the specification provides "ample disclosure" to enable an ordinary skilled in the art to prepare the prodrug. A close look at the description of prodrug on page 9 shows that the term refers to "any compound which releases an active drug according to formula I in vivo." such an definition is broad and it does enable one skilled in the art to determine how the prodrug is converted to active compounds, by what mechanisms and at what site the prodrug will be activated, what in vivo enzymes are likely involved in cleaving the protected group, etc. All these factors are uncertain

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and require one skilled in the art to spend undue amount of time to practice the invention. For these reasons, the rejection is maintained.

The rejection to claims under 112, second paragraph, is hereby withdrawn. Applicants have pointed out the support in the specification for terms used in the claims.

In amended claim 1, it appears that "R should be "R₂" in the definition of A. In addition, due to the restriction, X and Y should be limited to CH.

Claim Rejections - 35 USC § 102

Claims 1-5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Barton et al. (J. Am. Chem. Soc., 1993). Applicants argue that the difference of the claimed compounds and the reference compound is that one is alkyl and the other one is CF₃. Since applicants do not define specifically that the term "alkyl" refers to unsubstituted alkyl, the term should be given the broadest interpretation that includes fluorine substituted alkyl. *overcome*

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. Applicants are wrong in characterizing that "B" of the compound of formula I corresponds to the pyrimidine ring of the reference compound. The pyrimidine ring should correspond to R1 of the instant invention. Thus, the reference compound still anticipates the instantly claimed compounds.

All the rest of the rejections under 102(b) and 103(a) in the previous office action are hereby withdrawn. Applicants have amended the claims to overcome the rejections.

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Claim Rejections - 35 USC § 102

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Billman et al. (J. Org. Chem., 1962). Billman teaches the compound of the instant invention (see Compound V).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Katritzky et al. (Synthetic Communications, 1993). Katritzky teaches the compound of the instant invention (see Compound 5).

Claim Rejections - 35 USC § 103

Claims 1-5, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dinsmore et al. (Bioorganic and Medicinal Chemistry, 1999). Dinsmore et al. teach a generic group of diarylether derivatives (See formula I, Col. 4, P. 3), in particular, where instant R is alkoxyalkyl, acyloxyalkyl, etc. (See Table 3, Compounds 8a and Table 4). Compound 8a differs from the claimed compounds only in the nature of the substituent on the nitrogen atom (R is H in reference and R1 is alkyl in the instant invention). However, the reference teaches the equivalence of H and alkyl in the definition of R (see compound 5b and 9 wherein R is n-Bu). Thus, one of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. See *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

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Conclusion

1. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on March 7, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of


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this application or proceeding should be directed to the Group receptionist whose number is (703)
308-1235.

hl
May 2, 2002


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624